**510(k) Summary**

**Company** Ethicon Endo-Surgery, LLC
475 Calle C
Guaynabo, PR 00969

**Contact** Brian Godwin, RAC
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Ethicon Endo-Surgery, Inc.
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**Date Prepared** 20 November 2013

**Device Name**

Trade Name: HARMONIC FOCUS Shears + Adaptive Tissue Technology
Common Name: Instrument, Ultrasonic Surgical

**Classification Name**

Instrument, Ultrasonic Surgical (Unassigned, Product Code LFL)

**Predicate Device**

HARMONIC FOCUS® Shears, cleared under K100597 on 07 April 2010

**Device Description**

The Ethicon Endo-Surgery HARMONIC FOCUS Shears + Adaptive Tissue Technology is a sterile, single-patient use surgical instrument consisting of a soft grip scissor handle housing assembly with two hand controls (MIN for minimum power level and MAX for maximum power level). The instrument's working length is 9 cm in length with a 16 mm active blade length. The instrument allows for the cutting and coagulation of vessels up to and including 5 mm in diameter.

**Indications for Use**

The HARMONIC FOCUS Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

**Technological Characteristics**

The HARMONIC FOCUS Shears + Adaptive Tissue Technology use an EEPROM memory chip that stores device identification, usage tracking, and operating parameters for use by the Generator G11 that provides power for the HARMONIC FOCUS Shears + Adaptive Tissue Technology. Adaptive Tissue Technology refers to the power output algorithm that is utilized by the devices. During use, the Adaptive Tissue Technology algorithm parameters stored on the device EEPROM are read by the generator and used to reduce the power (current) to the instrument and provide a secondary, higher pitched generator activation tone as Adaptive Tissue Technology regulates the delivery of energy. To do this the generator monitors the thermal condition of the blade during device activation.

**Performance Data**

*Non-clinical and Preclinical Performance Testing*

Biocompatibility studies, electrical safety testing, and EMC testing were performed. The results demonstrate the HARMONIC FOCUS Shears + Adaptive Tissue Technology device performance was equivalent to the predicate. In addition, preclinical laboratory evaluations in an animal model were performed, which included acute and 30-day chronic survival studies. The results of those evaluations demonstrate that the HARMONIC FOCUS Shears + Adaptive Tissue Technology effectively cut and coagulated vessels 1 to 5mm in diameter.

*Clinical Performance*

This premarket notification does not rely on data from human clinical trials to demonstrate substantial equivalence. Clearance was based on non-clinical and preclinical testing.

**Conclusion**

The results of the bench testing and laboratory evaluations in an animal model demonstrate that the HARMONIC FOCUS Shears + Adaptive Tissue Technology are as safe and effective and perform as well as the identified legally marketed predicate devices for cutting and coagulating soft tissue and sealing vessels up to 5 mm in diameter, as measured in situ.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Ethicon Endo-Surgery, Inc.
Mr. Brian Godwin, RAC
Senior Regulatory Affairs Associate
4545 Creek Road
Cincinnati, Ohio 45242

December 3, 2013

Re: K133314
Trade/Device Name: HARMONIC FOCUS® Shears + Adaptive Tissue Technology
Regulatory Class: Unclassified
Product Code: LFL
Dated: October 25, 2013
Received: October 29, 2013

Dear Mr. Godwin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joshua C. Nipper -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

**Indications for Use**

510(k) Number (if known): K133314

**Device Name:**

HARMONIC FOCUS® Shears + Adaptive Tissue Technology

**Indications for Use:**

The HARMONIC FOCUS® Shears + Adaptive Tissue Technology are indicated for soft tissue incisions when bleeding control and minimal thermal injury are desired. The instrument can be used as an adjunct to or substitute for electrosurgery, lasers, and steel scalpels in general, otorhinolaryngologic (ENT), plastic, pediatric, gynecologic, urologic, exposure to orthopedic structures (such as spine and joint space) and other open procedures.

| | | |
|---|---|---|
| Prescription Use ___X___<br>(Part 21 CFR 801 Subpart D) | AND/OR | Over-The-Counter Use _____<br>(21 CFR 801 Subpart C) |

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A for BSA

(Division Sign-off)
Division of Surgical Devices
510(k) Number K133314